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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/807,979	03/24/2004	Assaf Govari	BIO-5044	4469
27777	7590	03/23/2010	EXAMINER	
PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			PEIFFLEY, MICHAEL F	
ART UNIT		PAPER NUMBER		
3739				
NOTIFICATION DATE		DELIVERY MODE		
03/23/2010		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jnjuspatent@corus.jnj.com  
lhhowd@its.jnj.com  
gsanche@its.jnj.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/807,979	<b>Applicant(s)</b> GOVARI, ASSAF
	<b>Examiner</b> Michael Peffley	<b>Art Unit</b> 3739

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 02 March 2010.
- 2a) This action is FINAL.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1 and 7-11 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1 and 7-11 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 24 March 2004 is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO/SB/06)  
 Paper No(s)/Mail Date \_\_\_\_\_
- 4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date \_\_\_\_\_
- 5) Notice of Informal Patent Application  
 6) Other: \_\_\_\_\_

***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 2, 2010 has been entered.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 7-11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is no support in the original disclosure for transducers arranged circumferentially around the longitudinal axis of a catheter and on a plane orthogonal to the longitudinal axis and adapted to treat tissue in a range of azimuths with respect to the longitudinal axis of less than 360. The specification makes no mention of the word "orthogonal", and the figures appear to show the transducers are arranged parallel to the longitudinal axis. For example, Figures 1 and 2 show transducers (34) that are located circumferentially around the central axis (38) and they

extend longitudinally along and parallel to the axis (38) to treat tissue at an azimuth with respect to the longitudinal axis. Figures 5a and 5b appear to show transducers that may be deemed to be mounted on a plane orthogonal to the longitudinal axis. However, these transducers do not treat tissue in a range of azimuths with respect to the longitudinal axis. Rather, these transducers direct energy in a forward direction directly into tissue.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 7-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear in claim 1 how circumferentially arranged transducers that are mounted on a plane orthogonal to the longitudinal axis of the device may treat tissue located in a range of azimuths with respect to the longitudinal axis. That is, transducers mounted orthogonally to the longitudinal axis would transmit energy along the axis, and not in a direction laterally away from the longitudinal such that a range of azimuths may be treated. It appears applicant is claiming properties from two different embodiments in a manner that is incapable of being combined. As such the claims are unclear.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1 and 7-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hadjicostis et al (2004/0254570) in view of the teaching of Chihara et al (5,273,045).

Hadjicostis discloses an apparatus comprising a catheter (70) having a longitudinal axis and having a distal portion (80). An ultrasound array (90) is arranged at the distal portion of the catheter and includes a plurality of transducer circumferentially arranged around the longitudinal axis (see Figure 3). The arrayed may be operated in a phased array mode to apply ablating energy to tissue of the subject in a range of azimuths that is less than 360 degrees (see paragraph [0042]). Hadjicostis also discloses a detection functionality to determine a portion of tissue and a location in the body, including feedback to control the array to set the range of azimuths to treat targeted tissue (paragraphs [0040-0043]). The only feature not expressly taught by Hadjicostis is the array of transducers located on a plane orthogonal to the longitudinal axis.

As addressed above, the claim is unclear with respect to the orthogonal placement of the transducers, particularly with transducers that provide energy in a range of azimuths. Applicant has two different embodiments. One embodiment has transducers arranged parallel to the longitudinal axis to provide energy in a range of azimuths. This embodiment is substantially identical to the Hadjicostis et al catheter. Regarding the orthogonal placement of the transducers, Chihara et al disclose another catheter having a transducer array, and Chihara et al specifically teach the transducers

may be arranged in an orthogonal manner (Figure 5) as an alternative to the longitudinally extending transducers as shown in Figure 3. The examiner maintains that it would have been an obvious modification for one of ordinary skill in the art to have provided the Hadjicostis catheter with orthogonally arranged transducers to direct energy in a desired direction, particularly since Chihara et al teach it is known to provide transducers arranged in such a manner on a similar catheter device.

Regarding claims 7-11, Hadjicostis et al fully disclose a detection functionality that may include the transducers to image tissue, or other imaging means that may be used to determine the location of the device relative to the desired tissue location.

### **Conclusion**

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Seward et al (6,059,731) and Stephens et al (6,780,157) disclose catheters having an ultrasound array arranged circumferentially around and extending along the longitudinal axis of the catheter. Marcus et al (5,295,484) discloses a catheter having an orthogonally arranged ablation/imaging transducer (Figures 8-9) and teach the transducer may be provided as a phased array of transducers.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Peffley whose telephone number is (571) 272-4770. The examiner can normally be reached on Mon-Fri from 7am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael Peffley/  
Primary Examiner, Art Unit 3739

/mp/  
March 16, 2010